

REMARKS


Applicant respectfully requests consideration of newly added claims 13-48. Claims 43-48 are copied from US Patent No. 6,174,516 for purposes of preserving rights under 35 U.S.C. § 135. The '516 patent issued January 16, 2001 and the above claims 43-48 are hereby copied within 1 year of issuance.

Support for the claims can be found at page 2 line 19 to page 3 line 29 of provisional application no. 60/004,258 where sequential application of an alkalizing agent and a peroxide-containing or peroxide releasing tooth bleaching composition is disclosed. The tooth surface pH prior to or during contact with the tooth bleaching composition is disclosed as between 7 and 10. Rinses, gels or pastes are disclosed. The term "paste" includes dentifrices which include abrasives intended to be brushed on the tooth surface. Alternatively, page 2 lines 13-14 of USSN 08/719,569 describe tooth whitening procedures that combine mechanical agitation and chemical processes. Urea peroxide is a peroxide releasing compound.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at the number below.

Respectfully submitted,

Dated: January 16, 2002



John P. Ivanicki, Reg. No. 34,628
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Version of Amendments with Markings to Show Changes Made

On page one, at paragraph one, line 7, after the subtitle "Related U.S. Application(s)," please delete the first paragraph:

[The present application is a continuation of United States Application Serial No. 09/192,609, filed on November 16, 1998, itself a divisional of United States Application Serial No. 08/719,569, filed on September 25, 1996, which issued on July 13, 1999 as U.S. Patent No. 5,922,307, and which claims priority from Provisional Application Serial No. 60/004,258, filed September 25, 1995, all of which are hereby incorporated by reference.]

and replace it with the following paragraph:

This application is a continuation of United States Application Serial No. 10/000,658, filed October 31, 2001; which is a continuation of United States Application Serial No. 09/374,172, filed on August 13, 1999; which is a continuation of United States Application Serial No. 09/054,156, filed April 2, 1998; itself a divisional of United States Application Serial No. 08/719,569, filed on September 25, 1996, which issued on July 13, 1999 as U.S. Patent No. 5,922,307; and which claims priority from Provisional Application Serial No. 60/004,258, filed September 25, 1995; all of which are hereby incorporated herein by reference.

202710-96T0500F

COPY

PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(b)(1).

DOCKETED

Atty. Docket: 1910/110

[+]

Inventor(s)/Applicant(s):

Last Name

First Name

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Montgomery

Robert

E.

Residence (City/State/Country):

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Title of Invention:

IMPROVED METHOD OF WHITENING TEETH

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Enclosed Application Parts (check all that apply):

☒ Specification: Number of Pages - 4 ☐ Small Entity Stmt
☐ Claims: Number of Pages - ☐ Abstract
☐ Drawings: Number of Sheets - ☐ Other: _____

METHOD OF PAYMENT (check one):

<input checked="" type="checkbox"/> A check is enclosed for the Provisional filing fee	PROVISIONAL FILING FEE
<input type="checkbox"/> The Commissioner is hereby authorized to charge filing fees and credit Deposit Account 19-4972.	AMOUNT(S) \$ 150.00

☒ The invention was made by an agency of the U.S. Government or under a contract with an agency of the U.S. Government.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

Signature

September 25, 1995

Date

Timothy M. Murphy

Typed or Printed Name

33,198

Registration No.

Additional inventors are being named on separately numbered sheets attached hereto.

PROVISIONAL APPLICATION FILING ONLY

EXPRESS MAIL CERTIFICATE UNDER 37 CFR 1.10

I hereby certify that the documents referred to as attached therein are being deposited with the United States Postal Service on the date indicated below in an envelope addressed "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 CFR 1.10, to Commissioner of Patents and Trademarks, Washington, DC 20231.

EXPRESS MAIL NO: EM221768862US

Brian M. Donovan

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PROVISIONAL APPLICATION FOR A PATENT
FOR
IMPROVED METHOD OF WHITENING TEETH

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PROVISIONAL PATENT APPLICATION FOR
IMPROVED METHOD OF WHITENING TEETH

5 I have discovered compositions and methods for bleaching tooth enamel *in situ* which allow the use of lower peroxide concentrations, such as hydrogen peroxide and carbamide peroxide, in tooth bleaching agents, and/or which allow effective tooth whitening in shorter contact times. A shorter contact time results in a limitation of tooth sensitivity and possible oral mucosal irritation which is so often seen with tooth bleaching products calling for contact times of greater than about 30 to 60 minutes, and sometimes
10 as long as 8 to 12 hours.

The critical aspect of the present invention is the pH of the tooth surface, which has been found to play a critical role in the speed at which stains are oxidized and thus eliminated as sources of tooth discoloration. A tooth surface pH of between 7.0 and 10.0,
15 and preferably between 7.5 and 9.0, is seen to result in a surprisingly rapid elimination of tooth staining when in contact with a peroxide-containing or peroxide-releasing composition.

For the purpose of this invention, the tooth surface is intended to mean that portion of a tooth which is directly responsible for the stained appearance of said tooth. The term
20 tooth surface generally means a tooth's acquired pellicle, plaque, enamel, and combinations thereof.

The pH of the tooth surface may be adjusted to a pH between 7.0 and 10.0 either prior to or during the tooth bleaching process. Tooth bleaching processes are well known in the prior art and may include the use of a custom made or "boil-and-fit" tray (also
25 known as a "splint"). Alternatively, the dental tray disclosed in the concurrently filed patent application entitled "Flexible Dental Tray" for an invention by Robert E. Montgomery and bearing attorney docket number 1910/101 may be used. Tooth bleaching compositions are also well known in the prior art and are primarily hydrogen peroxide-containing or hydrogen peroxide-releasing compositions formulated at a pH of
30 less than about 7.0, due to the inherent instability of hydrogen peroxide at a higher pH.

Thus, the prior art tooth whitening compositions and methods result in a tooth surface pH of less than about 7.0, due to limitations of composition stability.

It is well known in the paper and pulp bleaching art that the optimum pH for bleaching of cellulosic materials is about 10.5. However, insofar as (1) a tooth is
5 structurally a protein-inorganic composite, and (2) non-enamel tooth surface substances are either proteinaceous or partially proteinaceous in nature, a presumption regarding the ability of a tooth bleaching composition to more rapidly and efficiently whiten a tooth surface at a pH between 7.0 and 10.0 (versus a pH below about 7.0) is merely speculative. Most importantly, the tooth bleaching prior art does not disclose the benefit of a tooth
10 surface pH of between 7.0 and 10.0, and preferably between 7.5 and 9.0, with regards to the ability of peroxide-containing or peroxide-releasing tooth bleaching compositions to whiten teeth.

The most important health benefit of the present invention is that lower concentrations of peroxide can be utilized and/or shorter contact times can be prescribed in
15 order to achieve a desired tooth whitening effect, as compared to prior art compositions and methods. In light of the suggestion in the literature that the contact time of peroxide-containing or peroxide-releasing compositions be limited to less than about 15 minutes, the present inventive method and compositions are extremely useful.

The present inventive method can be practiced by (1) raising the tooth surface pH
20 to between 7.0 and 10.0 prior to and during contact with a peroxide-containing or peroxide-releasing tooth bleaching composition or (2) employing a tooth bleaching composition which will result in a tooth surface pH of between 7.0 and 10.0 during contact with said tooth.

The first approach utilizes an alkalizing agent, such as sodium hydroxide, sodium
25 carbonate, ammonium carbonate, and the like, as a rinse, paste or gel which is applied to the tooth surface prior to contact with the peroxide-containing or peroxide-releasing tooth bleaching composition. It is preferred to employ a composition with buffering capability, in order that the tooth surface pH can be maintained between 7.0 and 10.0 during the entirety of the tooth bleaching process.

An example of said tooth alkalizing agent is shown in Example 1, and an example of an aqueous tooth bleaching composition to be used following the Example I tooth alkalizing agent is shown in Example II.

Example I

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	Deionized water	87.20%
	SD Alcohol 38B	5.00%
	Potassium phosphate dibasic	5.00%
10	Poloxamer 407	2.50%
	Flavor	0.30%
	TOTAL	100.00%

The above composition has a pH of 8.8 at 25 deg C.

Example II

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	Distilled water (5 Megaohm-cm Minimum)	79.86%
	Carbopol 974P	2.00%
	Hydrogen Peroxide 35% (Super D/FMC Corp)	17.140%
20	Triethanolamine 99%	1.00%
	TOTAL	100.00%

The above example was prepared by dispersing the Carbopol 974P in the distilled water, reserving enough water to dissolve the triethanolamine for the final neutralization step.

25 This dispersion was heated, with agitation, to 75 deg C and allowed to cool, whereupon the hydrogen peroxide was added slowly while mixing. The triethanolamine was added (as a 20% solution) slowly to effect neutralization of the Carbopol 874P and achieve the final composition pH of 4.5. All equipment contact parts were constructed of Kynar-coated 316 Stainless Steel to prevent leaching of contaminant metals into solution.

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The second approach utilizes a peroxide-containing or peroxide-releasing tooth bleaching composition which results, upon contact with the tooth, in a tooth surface pH of

between 7.0 and 10.0. Said tooth bleaching composition may employ a single component system (such as an anhydrous sodium percarbonate gel buffered to a resulting aqueous pH between about 8.0 and 10.0) or a multi-component system (such as two gels which are combined immediately prior to use, said combination resulting in a hydrogen peroxide gel at a pH of between 7.0 and 10.0)

A particularly preferred single component system is the stabilized hydrogen peroxide gel shown in Example III and having a pH of 8.0.

Example III

10	Distilled water	86.41%
	Stabilizer Solution*	0.60%
	Carbopol 974P (BF Goodrich)	2.50%
	Hydrogen Peroxide 35% (PeroxyClean, FMC Corp)	10.30%
	Sodium Hydroxide Monohydrate (EM Suprapur Grade)	0.19%
15	TOTAL	100.00%

*Stabilizer Solution composed of the following:

	Dequest 2010 (Monsanto)	24,000 ppm
	Sodium Stannate Trihydrate (Goldschmidt)	35,000 ppm
20	Distilled water	qs to 100%

The above example was prepared by dissolving the stabilizer solution in the distilled water (reserving enough water to dissolve the sodium hydroxide for the final neutralization step), followed by dispersion of the Carbopol 974P in the distilled water/stabilizer solution. This dispersion was heated, with agitation, to 75 deg C and allowed to cool, whereupon the hydrogen peroxide was added slowly while mixing. The sodium hydroxide was added (as a 50% solution) slowly to effect neutralization of the Carbopol 974P and achieve the final composition pH of 8.0. All equipment contact parts were constructed of Kynar-coated 316 Stainless Steel to prevent leaching of contaminant metals into solution.